



Patent
Attorney's Docket No. 018413-378

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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| In re Patent Application of |) | BOX AF |
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| Charles RICCI <i>et al.</i> |) | Group Art Unit: 1617 |
| |) | |
| Application No.: 09/954,789 |) | Examiner: Shahn timer J. Sharareh |
| |) | |
| Filed: September 12, 2001 |) | |
| |) | |
| For: METHODS FOR TREATING |) | |
| ENDOLEAKS DURING |) | |
| ENDOVASCULAR REPAIR OF |) | |
| ABDOMINAL AORTIC |) | |
| ANEURYSMS |) | |

DECLARATION OF RICHARD J. GREFF PURSUANT TO 37 C.F.R. §1.132

The Assistant Commissioner for Patents
Washington, D.C. 20231
BOX AF

Sir:

I, RICHARD J. GREFF, hereby declare:

1. I am a joint inventor for the above-noted application.
2. In 1970, I received a Ph.D. in Polymer Chemistry from Polytechnic University, New York. I have more than thirty years experience in polymer chemistry, including over twenty-five years experience with medical devices and over eight years experience with the preparation and use of embolic compositions. I also have experience with the *in vivo* use in animals of embolic compositions and medical devices used to treat aneurysms.

3. I currently work as a consultant to several biomedical companies, and one of the companies I consult for is Micro Therapeutics, Inc., assignee of the entire right, title, and interest in this application.
4. I am familiar with the final Office Action received in the above-noted application and with the claimed invention. Specifically, I am aware that kits of parts comprising:
(a) fluid compositions, (b) a catheter suitable for delivery of the fluid composition,
(c) a catheter suitable for delivery of an endovascular prosthesis, and (d) an endovascular prosthesis comprising a stent graft capable of inhibiting blood flow into an abdominal aortic aneurysm are claimed.
5. I was present during the personal Interview with Examiner Sharareh conducted by Gerald F. Swiss, Esq. (Reg. No. 30,113) and Erin M. Dunston (Reg. No. 51,147) on December 4, 2002, concerning the final Office Action received in this application. At the Interview, Examiner Sharareh expressed concern that the claimed prosthesis is the same as that found in the publications cited in his Official Actions to reject the claims. Mr. Swiss, Mrs. Dunston, and I explained that the claimed stent graft prosthesis is *not* the same as the vascular stents or vascular grafts found in the cited publications: U.S. Patent No. 5,702,361 to Evans, U.S. Patent No. 5,443,454 to Tanabe, U.S. Patent No. 5,749,894 to Engelson, and U.S. Patent No. 5,695,480 to

Evans. I offered to submit a Declaration, based upon my experience in the field of vascular devices to treat aneurysms, explaining the difference between vascular stents, vascular grafts, and the claimed stent grafts. This is that Declaration.

6. **Vascular Stents** are cylindrical devices that are placed intraluminally to support and keep open a vascular (arterial) blood vessel. Vascular stents are most often constructed of metals (such as stainless steel, tantalum, and nitinol) for strength and flexibility, and are designed to have an open structure (such as mesh, ring, coil, and slotted tube) with a low metal to exposed artery ratio (less than 20%) to prevent occlusion and/or damage to the vascular wall. Stents are delivered intraluminally, usually over a catheter, and are positioned by balloon expansion or are self-expanding.

7. **Vascular Grafts** are natural (such as autologous saphenous vein and bovine carotid heterograft) or synthetic (such as Dacron or polytetrafluoroethylene ("PTFE")), tubular replacements for vascular (arterial) repair or replacement. Dacron grafts are woven or knitted, whereas PTFE grafts are biaxially stretched to produce a fibrillar microstructure. Vascular grafts are closed or impermeable, to prevent blood leakage. Vascular grafts are attached by suture in an open surgical procedure.

8. In contrast to either vascular stents or vascular grafts, **Stent Grafts** are combination devices that contain a vascular graft to repair or replace the diseased blood vessel, and stents for fixation and sealing of the ends of the device, intraluminally. Stent grafts are most successful in the treatment of AAA disease. Stent grafts are placed intraluminally over a catheter and anchored in the blood vessel by expansion (balloon expansion or self-expansion) of the stent portions of the device. The graft portion contains the blood flow and excludes the diseased portion of the blood vessel. The graft portion is constructed of known materials (Dacron polyester), with more recent designs containing additional support/anchoring structures. The sealing stent ends of the stent graft may contain supplemental anchoring devices, such as hooks or barbs. Stent grafts come in several configurations, including straight, tapered, or bifurcated. Stent grafts may be referred to as endovascular grafts because of the nature of their placement.

9. The distinctions between and among vascular stents, vascular grafts, and stent grafts was known to one of skill in the art at the time Applicants' invention was made. These distinctions are explained in a number of publications, which are being submitted as attachments to this Declaration. The enclosed publications may be categorized as follows:

Vascular Stents:

- i. STEDMAN'S MEDICAL DICTIONARY, 27th Edition, Lippincott Williams & Wilkins, eds., 2000, Page 1696.
- ii. DORLAND'S ILLUSTRATED MEDICAL DICTIONARY, 29th Edition, W.B. Saunders Co., 2000, Page 1698.
- iii. *Selection of Coronary Stents*, A. Colombo *et al.*, 40(6) J. AM. COLLEGE OF CARDIOLOGY 1021-1033.
- iv. *Stents for Intracoronary Placement: Current Status and Future Directions*, E. Eeckhout *et al.*, 27(4) J.A.C.C. 757-765.

Vascular Grafts:

- i. The Biomedical Engineering Handbook, Chapter 124, "Vascular Grafts," D. Nu & R. Allen, Pages 1871-1878, CRC Press, 1995.

Stent Grafts:

- i. *Endovascular Stent Grafts: Technology, Training and Proper Patient Selection, Combined Session: Vascular Surgery and Interventional Radiology*, J. Parodi, J.P.V.A. 1.1-1.2
- ii. *Endoleak after stent-graft treatment of abdominal aortic aneurysm: a meta-analysis of clinical studies*, G.W.H. Schurink *et al.*, 86 BRITISH J. SURGERY 581-587, 1999.

- iii. *Endovascular Management of "Endoleaks" After Transluminal Infrarenal Abdominal Aneurysm Repair*, T. J. Hölzenbein *et al.*, 16 EUR. J. VASC. ENDOVASC. SURG. 208-217, 1998.
- iv. *Comparison of first- and second- generation prostheses for endoluminal repair of abdominal aortic aneurysms: A 6-year study with life table analysis*, J. May *et al.*, 32(1) J. VASCULAR SURGERY 124-129, 2000.
- v. *Embolotherapy of Persistent Endoleaks after Andovascular Repair of Abdominal Aortic Aneurysm with the Ancure-Endovascular Technologies Endograft System*, N. Amesur *et al.*, 10(9) J.V.I.R.1175-1182, 1999.
- vi. *Endoluminal repair of infrarenal abdominal aortic aneurysms using a modular stent-graft: one-year clinical results from a European multicentre trial*, R. P. Tutein Nolthenius *et al.*, 7(5) CARDIOVASCULAR SURGERY 503-507, 1999.
- vii. *Endovascular aneurysm repair in high-risk patients*, T. A.M. Chuter *et al.*, 31(1:1) J. VASCULAR SURGERY 122-133, 2000.
- viii. *AneuRx stent graft versus open surgical repair of abdominal aortic aneurysms: Multicenter prospective clinical trial*, C. K. Zarins *et al.*, 29(2) J. VASCULAR SURGERY 292-308, 1999.
- ix. *Realistic Expectations for Patients with Stent-graft Treatment of Abdominal Aortic Aneurysms. Results of a European Multicentre Registry*, Ph. Cuypers *et al.*, 17 EUR J. VASC. ENDOVASC. SURG. 507-516, 1999.

- x. *Endoluminal abdominal aortic aneurysm surgery*, K.R. Woodburn *et al.*, 85
BRITISH J. SURGERY 435-443, 1998.

Wallstent and Wallgraft:

- i. *Biocompatibility and Performance of the Wallstent and the Wallgraft, Jostent, and Hemobahn Stent-Grafts in a Sheep Model*, M. Cejna *et al.*, 13(8) J.V.I.R. 823-830, 2002.

- 10. One publication, "*Biocompatibility and Performance of the Wallstent and the Wallgraft, Jostent, and Hemobahn Stent-Grafts in a Sheep Model*," by M. Cejna *et al.*, provides an excellent description of stent grafts, as it describes an *in vivo* comparison of three stent grafts. Specifically mentioned in this publication is a Wallgraft, a type of stent graft. *See Page 824, Description of Figure 1, of the Cejna publication.* Wallgraft, stent graft, and Wall stent graft (as mentioned in Applicants' Example 3, at Page 27 of the application) are synonyms.
- 11. Based on both the content of the publications cited above and my personal experience, it is my opinion that stent grafts are their own entities, and may not be considered as either vascular stents or vascular grafts. The differences between and among vascular stents, vascular grafts, and stent grafts is known throughout the art.

12. I hereby declare that all statements made herein are of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under § 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Date:

1/27/03

Richard J. Greff
Richard J. Greff, Ph.D.